K123702

510(k) Summary

MAR 1 1 2013

ADMINISTRATIVE INFORMATION

Manufacturer Name:	X-spine Systems, Inc. 452 Alexandersville Rd. Miamisburg, OH 45342 Telephone (937) 847-8400 FAX (937) 847-8410
Official Contact:	David Kirschman, M.D. Chief Medical Officer
Date Prepared:	10/30/2012

DEVICE NAME

Trade/Proprietary Name:	Silex™ Sacroiliac Joint Fusion System
Common Name:	Sacroiliac Joint Fixation / Sacroiliac Joint Fusion
Device Class:	Class II
Regulation Number:	§888.3040
Product Code:	OUR
Classification Name:	Smooth or threaded metallic bone fixation fastener

ESTABLISHMENT REGISTRATION NUMBER

The X-spine Systems, Inc. establishment registration number is 3005031160. The owner/operator number for X-spine Systems, Inc. is 9063903.

INTENDED USE

The Silex Sacroiliac Joint Fusion System is intended for fixation of large bones, including bones of the pelvis, for conditions including degenerative sacroiliitis and sacroiliac joint disruptions.

DEVICE DESCRIPTION

The Silex Sacroiliac Joint Fusion System consists of bone screws in various diameters, lengths and thread configurations to accommodate variations in patient anatomy. The Silex system is manufactured from Titanium alloy in accordance with ASTM F136, and the larger diameter (12.5mm) implants may optionally have the exterior surfaces plasma coated with medical-grade commercially pure titanium (CP Ti) per ASTM F1580. All implants will be provided non-sterile, and are intended for single use only and should not be reused under any circumstances.

EQUIVALENCE TO MARKETED PRODUCT

X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Silex Sacroiliac Joint Fusion System is substantially equivalent to predicate devices based on a comparison including the following characteristics:

- FDA Product Code
- Intended Uses
- Surgical Approach
- Anatomical Region
- Implant Materials
- Product Dimensions
- Mechanical Performance

PREDICATE DEVICES

- Synthes (USA) – 6.5mm Cannulated Screw (K021932)
- Zyga Technology, Inc. – SImmetry Sacroilliac Joint Fusion System (K102907)
- SI-Bone, Inc. – SI Joint Fusion System (K092375)

PERFORMANCE DATA

The implant components were tested using the following standards:

ASTM F543 – *Standard Specification and Test Methods for Metallic Bone Screws*

- Annex 1 (A1) - Test Method for Determining the Torsional Properties of Metallic Bone Screws
- Annex 2 (A2) - Test Method for the Driving Torque of Medical Bone Screws
- Annex 3 (A3) - Test Method for Determining the Axial Pullout Strength of Medical Bone Screws

ASTM F2193 – *Standard Specification and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System*

- Annex 4 (A4) - Test Method for Measuring the Static and Fatigue Bending Strength of Metallic Spinal Screws

In conclusion, biomechanical testing results indicate that the Silex Sacroiliac Joint Fusion System is substantially equivalent to predicate device performance and is capable of safely and effectively performing in accordance with its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

March 11, 2013

X-Spine Systems, Inc.
David Kirschman, M.D.
452 Alexandersville Rd.
Miamisburg, OH 45342

Re: K123702
Trade/Device Name: Silex sacroiliac joint fusion system
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR
Dated: Jan. 30, 2013
Received: Feb. 8, 2013

Dear Dr. Kirschman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123702

Device Name: Silex™ Sacroiliac Joint Fusion System

Indications for Use:

The Silex Sacroiliac Joint Fusion System is intended for fixation of large bones, including bones of the pelvis, for conditions including degenerative sacroiliitis and sacroiliac joint disruptions.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices